## REMARKS

Claims 1-20 are pending. All claims stand rejected. Claim 5 stands rejected under 35 U.S.C. §112 due to a formal matter regarding an antecedent. An appropriate change has been made to meet this rejection. Claims 1-4 stand rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 6,299,590 to Lüscher. Claims 5-7 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lüscher in view of United States Patent No. 5,236,443 to Sontag. Claim 8 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Lüscher in view of United States Patent No. 6,702,786 to Olovson. Claims 1 and 9-14 stand rejected under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 5,441,507 to Wilk et al in view of Lüscher. Claims 15-18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 5,569,270 to Weng in view of Lüscher. Claims 19 and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Weng et al in view of Lüscher and further in view of Wilk.

The Interview of April 30, 2008

Applicant gratefully acknowledges the interview with the Examiner of April 30, 2008. In the interview, the undersigned pointed out particular limitations in Applicant's claims that are not disclosed in the art of record. The undersigned

also pointed out that the art of record did not disclose drawing a suture into a needle. The Examiner agreed to consider recitations reflecting this difference. Also, in accordance with the Examiner's request, the undersigned has laid out the independent claims in the "subparagraph format."

Overview

Claims 1-14 recite an apparatus and claims 15-20 recite a method in which a suture is drawn into a suturing apparatus and then expelled. In many surgical scenarios, a suture is already anchored at one end to a patient's bone. An opposite end of the suture is free, and must be manipulated. Applicant can manipulate this opposite end by drawing it into a needle and a syringe and then expelling it after having passed it through tissue.

An apparatus that expels suture material already within the apparatus is completely incapable of working with a suture having an end already secured to a patient. It is submitted that there is no issue that apparatus and methods disclosed in the art of record are essentially useless for Applicant's purposes. Additionally, drawing a suture into an apparatus of the art of record would render it unsuitable for its intended purpose. However, Applicant wishes to avoid any issue as to whether his recitations rely on use of apparatus to substitute for unique structural recitations. Applicant recites unique structure and methodology

Applicant's Suturing Instrument and Method

In Applicant's apparatus and method, a syringe is provided having a barrel, a plunger and a connector to which a needle is detachably mounted. The needle can receive a suture from outside of the apparatus. The barrel has a capacity to receive a predetermined size and length of suture and sufficient fluid to draw the suture from outside of the needle, through the needle and into the barrel. The suture can subsequently be hydrodynamically expelled from the barrel.

The needle comprises a lumen. A lumen opening is at a distal end of the needle. As explained in the specification at paragraphs [0030] and [0031], the opening is configured to enable the easy passing of a suture and the application of some force to the suture by the trailing edge of the opening without cutting the suture. The lumen opens to one side so that a sharp point of the needle extends forwardly of the lumen opening. A trailing edge trails a different portion of the lumen opening. A surgeon may take a loose end of the suture and insert it in the opening. The suture may then be hydrodynamically drawn into and through the needle and into the barrel. After the loose end of the suture is drawn into the suturing apparatus, there is suture material projecting from the needle.

The surgeon may push the needle to penetrate tissue. The projecting sharp point enters tissue followed by the lumen opening and the suture material

extending from the lumen opening and further followed by the trailing edge of the lumen opening. As the trailing edge enters the tissue, the suture extends along an outside surface of the suturing needle. Once the sharp tip and the portion of the syringe folded over the trailing edge emerge on the other side of the tissue, the syringe is operated to expel fluid. Fluid motion then carries the suture, including the free end, through and out of the needle. The free end of the suture is now on the other side of the tissue. The surgeon can now manipulate the suture. The prior art does not provide teachings with respect to enabling this operation. The prior art also does not disclose Applicant's recited structure or method steps.

Applicant's Recitations

Claim 1 recites a suturing instrument with a syringe having a barrel and a plunger and a detachably mounted needle. The barrel has the capacity to receive a suture as well as fluid to draw the suture into the syringe hydrodynamically. An elongated needle comprising a lumen has an opening which can receive or expel a suture. At line 11, Applicant has more explicitly pointed out that the lumen is included in the needle. This recitation is supported in the specification at paragraph [0031]. Lines 18 and 19 recite that the needle has a distal end configured with a sharp point extending forward of said opening to the lumen. Applicant further specifies at line 18 that the opening which has the

sharp point extending forward thereof also has a trailing edge. The recitation of "trailing edge" is supported in paragraph [0031].

The method of claim 15 recites providing an elongated needle including a distal end having a tip configured for passage with a suture through a tissue. A syringe is detachably connected to the needle's proximal end. A length of suture is selected and introduced into the needle as well as a quantity of liquid. The needle is then passed through tissue. After the suture is carried through tissue in this manner, the length of suture is expelled from the distal end of the needle by hydraulic force from a quantity of liquid in the syringe.

Claim 15 has been amended at lines 5-7 to further specify that the needle comprises a sharp point extending forward of an opening of said lumen and that the opening further comprises a trailing edge. This recitation is supported in the specification at paragraph [0031]. Claim 15 further points out at line 19 that the suture is folded over the trailing edge of the opening as the needle passes through tissue. This recitation is supported in the specification at paragraph [0030].

Similarly, claim 12 has also been amended to recite a needle having a sharpened forward projecting point and a trailing edge.

The Rejection Under 35 U.S.C. §112

Claim 5 is rejected as not having an antecedent for the term trailing edge. The amendment to claim 1 further describes the nature of the leading and trailing edges of the lumen in the needle, and provides the requisite antecedent for the recitation of trailing edge in claim 5. It is therefore submitted that this rejection has been avoided.

The Rejections Under 35 U.S.C. §102(b)

1. Lüscher

Claim 1 stands rejected under 35 U.S.C. §102(b) as being anticipated by Lüscher. Lüscher discloses a device which dispenses a thread-like implant material from a barrel and through a needle for implantation into issue, and does not disclose handling of a suture. Lüscher points out at column 4, line 56 through column 5, line 6 that a syringe 30 having a casing 31 housing a bobbin 10 on which a fiber 13 is wound. A free end of the fiber 13 is inserted into a tube 19 of a hollow needle 17. The plunger 32 is moved in a direction toward the outlet of the chamber 31. Fiber 13 is unwound from the bottom 10 as the fluid transports the fiber toward a distal opening 20 and then to the outside.

Applicant recites a particular needle structure suitable for use in Applicant's suturing apparatus. Applicant also specifically recites hydrodynamically propelling a suture. Lüscher makes no such disclosure. At

column 4, line 60 through column 5, line 3, Lüscher points out that his channel 4 must be either inserted into a hole in a body or inserted in an existing puncture. Lüscher does not disclose an apparatus for wherein a sharp point of a needle is inserted at a projecting edge, followed by a lumen opening and suture material folded over a trailing edge thereof. Also, Lüscher specifically teaches that liquid must not exit from his channel 4. This is a hydrostatic system. However, Applicant specifically recites a hydrodynamic system.

MPEP §2131 states, "**TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM.**" Since Lüscher does not disclose elements of Applicant's claim, a rejection under 35 U.S.C. §102(b) is inappropriate. It is therefore submitted that the rejection based on anticipation by Lüscher should be withdrawn.

The Rejections Under 35 U.S.C. §103(a)

1. Lüscher as a Base Reference

MPEP §2143.03 requires that, "All words in a claim must be considered in judging the patentability of that claim against the prior art." It is submitted that essential elements of Applicant's recitations are not shown in the art of record. The rejection must recognize and address elements recited in Applicant's claims that are not in the cited art. Where a rejection has not explained why every limitation in a claim would have been obvious to a person of ordinary skill in the

art, a case of prima facie obviousness is not made out. *Ex parte Wada and Murphy,* Appeal No. 2007-3733, (BPAI, January 14, 2008).

It is submitted that in the rejections discussed below, all the elements recited by Applicant are not addressed. Therefore, even assuming only for the sake of argument that the references meet the "KSR" criteria for combinability set out in MPEP §2143, a rejection under 35 U.S.C. §103(a) is not appropriate.

2. Lüscher in view of Sontag

Claims 5-7 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lüscher as applied to claim 1 in view of Sontag. The rejection takes the position that: Lüscher teaches the limitations of claim 5 except for a rounded tip of a suture needle; Sontag teaches a suturing needle with openings at the end that are slightly rounded to protect the surgeon from accidental cuts or punctures; and that it would have been obvious to use rounded needles in order to protect the user from accidental cuts. It is respectfully submitted that these grounds of rejection do not address the recitations of the claims.

Applicant recites in each independent claim, and, therefore, in all claims, a needle with a projecting sharp edge and a trailing edge. The projecting edge is defined, as for example in paragraphs [0030] and [0031], as a portion extending beyond an opening of a lumen. A trailing edge is one over which a

suture may be folded when a suture extends from within the lumen. Applicant explicitly defines a structure in which there are a projecting edge and a trailing edge adjacent an opening of a lumen.

Sontag discloses neither a projecting edge nor a trailing edge. At column 3, lines 7-10, Sontag states, "The distal portion 20 of the needle 12 defines a tapered portion whose cross sectional area decreases progressively toward a pointed or sharpened end of the needle." Sontag explicitly teaches a needle having a uniform structure surrounding and opening from a needle. Sontag explicitly teaches that there is neither a leading edge nor a trailing edge. Therefore, Sontag cannot supply the missing teachings. Since the rejection does not address each element of Applicant's recitations, under MPEP §2143.03, a rejection under 35 U.S.C. §103(a) is inappropriate. It is therefore submitted that the present rejection should be withdrawn.

3. Lüscher in view of Olovson

Claim 8 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Lüscher in view of United States Patent No. 6,702,786 to Olovson on the ground that Olovson discloses a needle cover to stiffen a needle.

Lüscher is incomplete as a base reference and as described above. Olovson does not disclose a means for stiffening a needle as recited by Applicant in claim 8. At column 6, lines 26 – 41, Olovson explains that a needle

protector 2' merely surrounds and protects the needle 14.There is no stiffening. The needle protector 2' corresponds to a shape of a container 10 and is axially movable to be in or out of axial registration with the needle 14. No stiffening function is disclosed.

Therefore, there is no demonstration of stiffening, which is what applicant is reciting. It is therefore submitted that this ground of rejection should be withdrawn.

4. Wilk in view of Lüscher

Claims 1 and 9-14 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wilk in view of Lüscher. The rejection essentially takes the position that Wilk discloses the elements of the claims but does not disclose that a suture distributor is a syringe. Lüscher is cited for the disclosure of a suture distributor that is a syringe.

It is respectfully submitted that this characterization of Wilk is unsupported by the record. Wilk does not disclose a suture distributor. Wilk expressly states that a purse-string suture is being executed to close tissue after organ stapling. By definition, a purse-string suture is executed by stitching in a circular pattern to invert or close an organ. Wilk's apparatus requires manipulation of the end of a needle to carry a suture in a circular pattern. There is no dispensing of a suture as in the case of applicant in which the end of a

suture is expelled from a needle after the needle has penetrated through a tendon or other tissue. There is also no dispensing of threadlike material as in Lüscher, in which progressively increasing amounts of threadlike material are amassed to form an implant.

The rejection characterizes element 140 of Wilk as a suture distributor. However, at column 11, line 63, element 140 is expressly described as a plunger or ejector rod. The rod 140 is used to eject a needle 130 through passages 126. There is no disclosure that any suture passes through the ejector rod 140. The rejection states that the needle 130 has a circular opening. There is no disclosure of any opening in the needle 130. At column 11, lines 56-60, the needle 130 is only described as flexible. The plunger rod 140 is pushed in a distal direction to eject the needle 132 from a tube (column 12, lines10-13). A grasping forceps 146 is used to move an end of needle 130 and a suture 148 attached thereto in order to manipulate the needle and surgery through tissue.(column 12, lines14 to 19).

Additionally, applicant recites a needle lumen in which a suture may be drawn in. Wilk makes no such disclosure.

Applicant's recitations cannot be rendered obvious in light of a disclosure that is not included in the reference. Therefore, it is submitted that this ground of rejection should be withdrawn.

5. Weng in view of Lüscher

Claims 15-18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 5,569,270 to Weng in view of Lüscher. The rejection states that Weng teaches a method of suturing which includes an elongate needle through which a suture may be hydrodynamically propelled. Lüscher is cited for the teaching of a suture.

Claims 16, 17 and 18 are dependent on claim 15. Therefore, distinguishing recitations in claim 15 distinguish claims 16-18 as well. Among the distinguishing recitations in claim 15 is that an end of a suture may be drawn into a needle. Applicant's method provides for enabling a surgeon to manipulate an end of a suture having an opposite end anchored to a bone. Weng's apparatus cannot do this.

Weng discloses an old scheme in which suture material on a spool can be expelled from the interior of a device by fluid pumped through the device. Weng only teaches unidirectional dispensing of suture material from within an apparatus. No method is provided for manipulating an end of a suture which may be secured to a patient. The rejection does not make any suggestion as to why a method that produces a very important result is rendered obvious by an apparatus that is not capable of performing be recited method.

It is therefore submitted that the rejection does not meet the requirements of MPEP §2143. Additionally, the analysis required by the Board in *Wada and Murphy, supra*, has not been made.

It is further submitted that the rejection of claims 15-18 is also avoided by the recitation in claim 15 utilizing a needle having a projecting sharp edge ahead of lumen and a trailing edge behind. The suture is moved through tissue by leading with a sharp point and carrying the suture therebehind, with a trailing edge of a lumen bearing against the suture. The art of record does not disclose this method of moving an end of a suture through tissue. This is another aspect the obviousness of which has not been alleged or demonstrated. It is therefore further submitted that the issue of obviousness is avoided and that the rejection under 35 U.S.C. §103(a) should be withdrawn.

6. Weng in view of Lüscher and further in view of Wilk

Claims 19 and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Weng et al in view of Lüscher and further in view of Wilk. Claims 19 and 21 are dependent on claim 15, and are therefore also distinguished as recited above.

Additionally, as described above, these references do not provide teachings specified above with respect to Applicant's recitations. It is therefore submitted that this ground of rejection merits withdrawal as well.

**Summary**

Applicant provides for operational advantages through the recited method and apparatus. One function that can be performed is the capture of a free end of the suture to a patient location, for example. Applicant explicitly recites structure in the apparatus claims and steps in the method claims which provide for performance of unique functions. Applicant has distinguished his recitations from the art of record as explained in detail above.

Applicant has demonstrated that elements cited in the art of record do not correspond to Applicant's recitations. Therefore, Applicant submits that the requirements of MPEP §2131 to demonstrate presence in the art of record of all recited elements to support an anticipation rejection under either 35 U.S.C. §102(b) are not met. Further, the requirement of MPEP §2143.03 to consider all limitations recited by Applicant in order to support a rejection under 35 U.S.C. §103(a) has not been met.

Applicant therefore respectfully submits that the application is now in condition for allowance. If it is believed that the application is not in condition for allowance, the Examiner is respectfully requested to contact the undersigned to expedite the prosecution of the application.

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